



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

JK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,766	01/17/2002	Richard J. Fitzpatrick	1932.1110-001	5568

21005 7590 10/25/2004

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/051,766	Applicant(s) FITZPATRICK ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11-19 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 10 is/are rejected.
- 7) ☒ Claim(s) 4, 6-8 and 20-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/26/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 04/26/04; terminal disclaimer, amendment and remarks filed 05/17/04.

Claim Rejections - 35 USC § 112

1. The rejection of claim 4 under 35 U.S.C. 112, first paragraph is withdrawn in light of the amendment.

Double Patenting

The submission of terminal disclaimer overcomes the obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. (US 4,217,429).

Wagner discloses the use of ionene polymer in treating antimicrobial infection (abstract, column 1, lines 22-26, columns 2 and 3); ant is known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation that overlaps a general teaching of inflammation. Wagner meets the limitations of the claims.

Art Unit: 1615

The following prior art are about as relevant as the art cited above as they use ionene-containing formulations to treat inflammations or conditions that are associated with inflammations.

Mandeville, III et al. (US 6,767,549) discloses treating microbial infection in a human mammal by administering therapeutically effective amount of a polymer that comprises an amino group or an ammonium group attached to the polymer backbone via an aliphatic spacer arm (abstract; column 2, lines 5-23; column 3, lines 45-67 and columns 4 and 5). Mandeville's polymer is ionene. Microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference).

Klofta et al. (US 6,238,682) discloses application of a lotion that contains antimicrobial agent (abstract; column 4, lines 55-66) and ionene polymer (column 16, line 23) is listed as an antibacterial. Microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference).

Drake et al. (US 5,419,897) discloses the administration of ionene polymer to treat helminth infections and infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference).

4. Claims 4, 6, 7, 8 and 20-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Withdrawn Claims

Claims 9, 11-19 and 25-32 remain withdrawn from consideration. Claim 1 is found not to be allowable. Thus the claims are not rejoined.

Art Unit: 1615

Provisional Rejection Under Obviousness-type Double Patenting

The provisional rejection of claims 1-8, 10 and 20-24 under obviousness-type double patenting is withdrawn because of the submission of terminal disclaimer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

